REMARKS

The office action of February 20, 2008 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 22-25, 28-30, 35-38, and 42-47 remain in this case, claims 45-47 being amended and claims 39-41 being cancelled by this response. No new matter has been added.

Attached are 37 CFR 1.132 Declarations by Bernhard Muellinger ("Muellinger Declaration"), an inventor of the present invention, William J. Zimlich, Jr. ("Zimlich Declaration"), an inventor of U.S. Patent No. 6,269,810, and Peter Brand ("Brand Declaration"), an inventor of U.S. Patent No. 6,606,989.

Rejections under 35 U.S.C. §112

Claims 22-25, 28-30 and 35-47 were rejected under 35 U.S.C. 112, first paragraph, as filing to comply with the written description requirement. The Applicant respectfully disagrees with this rejection.

Claim 25 was amended to include the language "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" and included in newly added claims 43 and 44 in the office action response dated May 2, 2007. No new matter was added. More specifically, this language is supported by page 2, lines 27-28 and page 3, lines 32-34 of the application as filed. The Applicant respectfully notes that the July 10, 2007 office action (the first office action issued after the May 2nd response was filed) did not include a written description rejection of this language in the claims. This indicates that the Examiner believed at that time that the written description requirement was satisfied with respect to the claim amendments made in the May 2nd response.

Similarly, the language that the Examiner is rejecting with respect to the following claims was also added in the May 2, 2007 response. No new matter was added.

Claim 37 is supported by column 8, line 21 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as amended in the office action response dated May 2, 2007.

Claim 39 is supported by column 8, lines 20-21 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as amended in the office action response dated May 2, 2007.

Claim 40 is supported by column 8, lines 1-10 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as amended in the office action response dated May 2, 2007.

Claim 41 is supported by column 8, lines 7-8 and 22-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as amended in the office action response dated May 2, 2007.

Claim 42 is supported by column 7, lines 16-18 and column 8, lines 29-30 of U.S. Patent No. 5,161,524, incorporated by reference in the application as filed, and by the present specification as amended in the office action response dated May 2, 2007.

Nevertheless, to further prosecution of the application, claims 39-41 have been cancelled. Reconsideration and withdrawal of the rejection of claims 22-25, 28-30, 35-38 and 42-47 are respectfully requested.

Objection to the Drawings

The drawings were objected to for not showing every feature of the invention specified in the claims. More specifically, The Examiner stated that the two conduits, the regulator, the housing, and the a venturi in the primary conduit must be shown in the figures or the features cancelled from the claims.

While Applicant respectfully disagrees with this objection, claims 39-41 have been cancelled to further prosecution of the application. Reconsideration and withdrawal of the objection are respectfully requested.

Rejection under 35 U.S.C. §102

Claims 24, 25, 28, 38-40 and 42-44 were rejected under 35 U.S.C. 102(e) as being anticipated by Brooker (6,269,810). Applicant respectfully disagrees with the rejection.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" (emphasis added). Claims 43 and 44 similarly claim "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters, comprising the substeps of: evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" and "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters, comprising the substeps of: evaluating the aerosol parameters for the inhalation; adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation", respectively (emphasis added).

Brooker does not disclose individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters. More specifically, Brooker does not disclose adjusting flow rate or tidal volume using individual patient parameters or aerosol parameters. Brooker states that "[i]t will be remembered that the pulmonary dosing system of the present invention does not include a respirator or the like, and is intended for use with patients who can breathe normally." (column 4, lines 31-35). The breathing pattern in Brooker is not adjustable in the device. The breathing pattern in Brooker is not controlled, since deposition is preferably measured during the inhalation treatment by using the radioactive tracer Tc99m. Once the data using the tracer has been collected, a physician is required to train and guide the patient. The device is not capable of being individually adjusted by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters.

Brooker does discuss tidal volume. "It has been found that it is especially useful for some therapies that the drug aerosol reaches the deep lung. The entire volume of each breath is called the 'inspired volume'. This inspired volume can be a normal breath, referred to as 'tidal volume', or could be a deep breath of much greater volume, referred to as a 'vital capacity' breath. With cooperation from the patient (in drawing a deep breath), the device enables this deep penetration by providing that the metered volume of drug aerosol from the plenum forms the first part of each inhaled breath (approximately equal to the tidal volume) and is followed by a volume of air which makes up the latter part of each inhaled breath (the remainder of the vital capacity). It has been determined that this air portion in the latter part of each breath tends to help push the initial drug portion down into the deep lung. If the drug made up most of the entire breath, then the latter part of each breath would not be delivered to the deep lung and may not be available for maximum benefit." (column 6, lines 12-29). Part of Brooker's method calculates "the number of breaths required from the patient" (column 7, line 28). Clearly, the patient's breathing accounts for the tidal volume and respiratory flow. The device is not able to adjust these parameters based on an individual patent. The device in Brooker only controls aerosol pulses, pulse lengths and the number of breaths. In addition, a major objective in Brooker is the safe inhalation of neoplastic drugs by capturing the exhaled aerosol. The inhalation device in Brooker is not intended for a routine inhalation at home.

By adjusting the respiratory flow or tidal volume of the inhalation device, the method of the present invention is able to optimize the dose of the active ingredient of an aerosol that is applied to a desired section of a lung of a patient, as claimed in claims 25, 43 and 44. Brooker does not disclose an optimal dose of at least one active ingredient of at least one aerosol being applied to a desired section of a lung of the patient during a controlled inhalation. As the attached Brand paper explains (filed as part of an IDS dated July 11, 2006), it is very difficult to optimize dosage of an active ingredient for an aerosol from patient to patient without controlling the breathing pattern of the patient. "The study has shown that within the study population the inhaled air volume and flow rate were quite different. Consequently, **total particle deposition varied between 20 and 95%, depending on breathing patterns**." (Brand, 1999, Abstract, page 724). "The dose depends on many factors that are difficult to control: particle deposition in the lungs strongly depends on particle size, lung structure and breathing pattern, with the result that particle deposition and thus the deposited dose varies considerably among patients." (Brand,

1999, p. 724, second column, first paragraph). "Although all patients were carefully trained at the beginning of their inhalation therapy to perform inhalations deeply and slowly, the breathing pattern was quite different among patients (Fig. 2)." (Brand, 1999, p. 726, second column, last paragraph). As discussed above, Brooker does not control or adjust tidal volume or respiratory flow. Therefore, Brooker does not disclose providing an optimal dose of at least one active ingredient of an aerosol to a desired section of a lung of a patient.

Amended independent claims 25, 43, and 44 also claim, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added). As discussed above, air flow and inhalation of the drug in Brooker requires cooperation from the patient. Air flow is not controlled through the inhalation device in Brooker.

In the present invention as claimed in claims 25, 43 and 44, during the breathing maneuver, the air flow is controlled by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed. Brooker does not disclose controlling an air flow through the inhalation device.

The differences between Brooker and claims, 25, 43, and 44 are also discussed in paragraphs 10-19 and paragraphs 10-17 of the Muellinger Declaration and the Zimlich Declaration, respectively.

Brooker does not disclose each and every element of Applicant's claims 25, 43, and 44. Therefore, it is respectfully suggested that the rejection of independent claims 25, 43 and 44 as being anticipated by Brooker is overcome. Claims 24, 25, 28, 38 and 42, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection of claims 24, 25, 28, 38 and 42-44 are respectfully requested.

Rejections under 35 U.S.C. §103

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker in view of Servidio (5,598,838). Applicant respectfully disagrees, and believe the claims, as

amended, are patentable over Brooker for the reasons given above in respect to the section 102 rejection of claim 25, from which claim 23 depends. The arguments above as to the novelty of claim 25 are repeated here by reference.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" (emphasis added).

Independent claim 25 also includes, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added).

Brooker does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters. Brooker does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters. Brooker states that "[i]t will be remembered that the pulmonary dosing system of the present invention does not include a respirator or the like, and is intended for use with patients who can breathe normally." (column 4, lines 31-35). The breathing pattern is Brooker is not adjustable in the device. The breathing pattern in Brooker is not controlled, since deposition is preferably measured during inhalation treatment by using the radioactive tracer Tc99m. Once the data using the tracer has been collected, a physician is required to train and guide the patient. The device is not capable of being individually adjusted by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters. Brooker also does not teach or suggest controlling an airflow through an inhalation device using the inhalation device during a controlled inhalation.

Servidio does not provide what Brooker lacks. More specifically, Servidio does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapating a dosage of at least one aerosol on the basis of the inhalation paramaters. Servidio also does not

teach or suggest adjusting flow rate or tidal volume based on the inhalation parameters. Servidio also does not teach or suggest controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation. Instead, Servidio teaches a pressure support ventilatory assist device with pressure regulation. Servidio mentions tidal volume; however, the tidal volume is just an inputted or outputted value, and one of a number of parameters that are measured during use of the device.

Servidio relates to a completely different field from the present invention. Servidio teaches supplying pressurized air to a patient in the treatment of obstructive sleep apnea. The treatment of sleep apnea, i.e. the intermittent obstruction of the upper airway occurring during sleep, is in no way linked to the administering of a controlled inhalation of therapeutic aerosol for a patient during breathing maneuvers according to claim 25. Servidio does not teach or suggest any type of aerosol dosing.

Furthermore, there is no motivation to combine Brooker's dosing system with Servidio's sleep apnea breathing device, nor would the combination teach or suggest the present invention. Each of the references teaches very different devices that perform different functions. A person of ordinary skill in the art of inhalers would not combine elements from pulmonary dosing system art with elements of sleep apnea device art.

The differences between Brooker and Servidio and claim 25 are also discussed in paragraphs 10-19 and 31-34 of the Muellinger Declaration.

Brooker and Servidio, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Brooker in view of Servidio. Claim 23, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations it contains. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22, 29, 30, 35, 36, 37 and 45-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker in view of Willemot (5,560,353). Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claim 25, upon which claims 22, 29, 30, 35, 36, 37 and 45 depend,

and the arguments regarding the anticipation of claims 43 and 44, upon which claims 46 and 47 depend, respectively, are repeated herein by reference.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" (emphasis added). Claims 43 and 44 similarly claim "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters, comprising the substeps of: evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" and "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters, comprising the substeps of: evaluating the aerosol parameters for the inhalation; adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation", respectively (emphasis added).

Amended independent claims 25, 43, and 44 also include, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added).

Regarding claims 25, 43, and 44, Willemot does not provide what Brooker lacks. More specifically, Willemot does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters. Willemot also does not teach or suggest adjusting flow rate or tidal volume based on the individual patient parameters or the aerosol parameters. Willemot does not teach or suggest the inhalation device controlling air flow during the

breathing maneuver. Instead, Willemot teaches a system that supplies puffs of gas containing particles of an active product to a patient. This gas is only used to drive the aerosol generation system. The gas does not provide the whole inhalation flow rate or inhalation volume. Willemot teaches a metered dose inhaler. "Breath phases of the patient are sensed for initiating each of the puffs at the correct point in the breath cycle, and for counting the puffs. The sequence of puffs is programmably controlled and the puffs in a predetermined sequence according to a puff sequence program." (Abstract). The system senses breath phases of a patient; it does not adjust them in any way. Therefore, Willemot does not adjust an inhalation device to a patient by adapting a dosage of at least one aerosol, nor does Willemot adjust flow rate or tidal volume based on individual patient parameters or aerosol parameters.

The differences between Brooker and Willemot and claim 25 are also discussed in paragraphs 10-19 and 35-38 of the Muellinger Declaration.

Brooker and Willemot, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brooker in view of Willemot. Claims 22, 29, 30, 35, 36, 37 and 45, 46 and 47 being dependent upon and further limiting claims 25, 43, and 44, respectively, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 41 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker in view of Willemot and Howe (6,070,573) Although Applicant respectfully disagrees with this rejection, claim 41 has been cancelled to further prosecution of this application. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 24, 25, 28, 38-40 and 42-44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989) in view of Brooker. Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claims 25, 43 and 44 over Brooker, are repeated herein by reference.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation

parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation". Claims 43 and 44 similarly claim "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters, comprising the substeps of: evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" and "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters, comprising the substeps of: evaluating the aerosol parameters for the inhalation; adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation", respectively.

Amended independent claims 25, 43, and 44 also claim, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added).

In the present invention as claimed in claims 25, 43 and 44, during the breathing maneuver, the air flow is controlled by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed.

In Brand, flow rates and volumes can be selected by the user by entering values for inhalation volume and inhalation flow rate. However, this selection does not result in an optimal dose of at least one active ingredient of at least one aerosol being applied to a desired section of a lung of a patient during a controlled inhalation. Brand does not teach or suggest a device that is individually adjusted by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters. In addition, Brand does not teach or suggest

adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters or aerosol parameters or controlling the air flow through the inhalation device.

While Brand teaches having the user select flow rates and volumes by entering values for inhalation volume and inhalation flow rate, even a trained physician or a trained nurse is not able to guide a patient so that the patient inhales with an optimum flow rate and volume. The Applicant has shown published clinical data from Köhler et al. that show that, even when patients are guided, they do not inhale with the optimum flow rate and inhalation volume, as shown in the published clinical data from Köhler et al (Journal of Aerosol Medicine, 2005, submitted in the IDS dated July 11, 2006, copy attached). Köhler specifically states that "All the CF patients have been regularly trained for several years in manually triggered inhalation by a physiotherapist (i.e. to press the interrupter immediately prior to the start of inhalation and to release the interrupter immediately after the end). They were instructed to inhale deeply and slowly." (Köhler, page 388, column 1, third full paragraph). Despite these instructions, "it was found that inhalation with the electronically controlled inspiration flow by means of AKITA permitted a deposition that was 46% (range 3-162%) higher and more peripheral than the conventional mode.... The improvement noted for deposition was obviously attributable to the controlled breathing maneuver alone." (Köhler, page 391, first full paragraph).

As discussed above with respect to the rejection of claims 25, 43, and 44, Brooker does not provide what Brand lacks.

The differences between Brand and/or Brooker and claims 25, 43 and 44 are also discussed in paragraphs 10-19 and 21-30 of the Muellinger Declaration, paragraphs 10-21 of the Zimlich Declaration and paragraphs 10-20 of the Brand Declaration.

Brand and Brooker, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brand in view of Brooker. Claims 24, 25, 28, 38 and 42, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brand in view of Brooker and Servidio. Applicant respectfully disagrees. The arguments regarding the obviousness of claim 25, upon which claim 23 depends, over Brand in view of Brooker, is repeated herein by reference.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" (emphasis added).

Independent claim 25 also includes, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added).

Servidio does not provide what Brand and Brooker lack. More specifically, Servidio does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapating a dosage of at least one aerosol on the basis of the inhalation paramaters. Servidio also does not teach or suggest adjusting flow rate or tidal volume based on the inhalation parameters, nor does Servidio teach or suggest controlling an airflow through an inhalation device using the inhalation device during a controlled inhalation. Instead, Servidio teaches a pressure support ventilatory assist device with pressure regulation. Servidio mentions tidal volume; however, the tidal volume is just an inputted or outputted value, and one of a number of parameters that are measured during use of the device.

The differences between Brand, Brooker and Servidio and claim 25 are also discussed in paragraphs 10-19 and 21-34 of the Muellinger Declaration.

Brand, Brooker and Servidio, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Brand, Brooker in view of Servidio. Claim 23, being dependent upon and further limiting claim

25, should also be allowable for that reason, as well as for the additional recitations it contains. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22, 29, 30, 35, 36, 37 and 45-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brand in view of Brooker and Willemot (5,560,353). Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claim 25, upon which claims 22, 29, 30, 35, 36, 37 and 45 depend, and the arguments regarding the anticipation of claims 43 and 44, upon which claims 46 and 47 depend, respectively, over Brand and Brooker are repeated herein by reference.

Independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, comprising the substeps of: evaluating the inhalation parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" (emphasis added). Claims 43 and 44 similarly claim "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters, comprising the substeps of: evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation" and "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters, comprising the substeps of: evaluating the aerosol parameters for the inhalation; adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of a lung of the patient during the controlled inhalation", respectively (emphasis added).

Independent claims 25, 43, and 44 also claim, in part, the step of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" (emphasis added). In the present invention as claimed in claims 25, 43 and 44, during the

breathing maneuver, the air flow is controlled by the inhalation device. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed.

Regarding claims 25, 43, and 44 Willemot does not provide what Brand and Brooker lacks. More specifically, Willemot does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters. Willemot also does not teach or suggest adjusting flow rate or tidal volume based on the individual patient parameters or the aerosol parameters. Willemot also does not each or suggest air flow controlled by an inhalation device during a breathing maneuver. Instead, Willemot teaches a system that supplies puffs of gas containing particles of an active product to a patient. This gas is only used to drive the aerosol generation system. The gas does not provide the whole inhalation flow rate or inhalation volume. Willemot teaches a metered dose inhaler. "Breath phases of the patient are sensed for initiating each of the puffs at the correct point in the breath cycle, and for counting the puffs. The sequence of puffs is programmably controlled and the puffs in a predetermined sequence according to a puff sequence program." (Abstract). The system senses breath phases of a patient; it does not adjust them in any way. Therefore, Willemot does not adjust an inhalation device to a patient by adapting a dosage of at least one aerosol, nor does Willemot adjust flow rate or tidal volume based on individual patient parameters or aerosol parameters.

The differences between Brand, Brooker and Servidio and claim 25 are also discussed in paragraphs 10-19, 21-30 and 35-38 of the Muellinger Declaration.

Brand, Brooker and Willemot, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brand in view of Brooker and Willemot. Claims 22, 29, 30, 35, 36, 37 and 45, 46 and 47 being dependent upon and further limiting claims 25, 43, and 44, respectively, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 41 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brand, in view of Brooker, Willemot, and Howe. Although Applicant respectfully disagrees with this

rejection, claim 41 has been cancelled to further prosecution of this application. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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